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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,138

06/23/2003

Robert Lammle

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EXAMINER

TRAIL, ALLYSON NEEL

ART UNIT

PAPER NUMBER

2876

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/602,138

Applicant(s)

LAMMLE, ROBERT

Examiner

Allyson N. Trail

Art Unit

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11, 13-15, and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 9, 11, 13-15, 17-24, and 26 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 6, 8, 10 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Amendment

1. Receipt is acknowledged of the amendment and filed August 14, 2006.

Claim Objections

2. Claim 26 is objected to because of the following informalities:

Re claim 26, line 2: replace "comply" with --complies--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 5, 9, 11, 13-15, 17, 19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung (2003/0006878) in combination with Bain (2005/0021175) and in further view of Hooper et al (5,442,239), hereinafter Hooper.

Chung teaches the following in regards to claims 1, 11, 13, and 14:

Chung teaches a method for providing pharmaceutical information to a patient.

The method of providing information includes dispensing a pharmaceutical product having an electronically identifiable tag associated with the product.

Specifically, Chung discloses in paragraph 0141, when filling a prescription, a smart tag reader at the pharmacy or other dispenser reads the prescription smart tag 410 and produces or generates a pick list 410 from which a pharmacist or other

dispensing agent can fill the prescription. The pharmacy fills the prescription and labels 420 each item dispensed with a smart tag in which is stored the medication and prescription information. The pharmacy also applies a conventional human-readable printed label which may also include bar-coded information.

In paragraph 0142, Chung teaches the medication smart tag and prescription smart tag being read and cross checked 430 for completeness and accuracy. Such reader maybe linked to access 440 a relational database for comparing the information read from the smart tags with a medical database for verifying and/or identifying allergy, drug interaction, diagnostic or other information.

With respect to claims 5 and 15, Chung teaches using a display 50 (touch screen display 50) for providing an easy to use and convenient combined display 50 and input means 52 through which information may be provided and information and requests may be received. (See paragraph 0086).

Chung teaches the following in regards to claim 17:

"Desirably, processed information and/or transactional information should be available in human readable form, such as by display on a computer monitor or by print out by a computer printer, both of which may be conventional." (Paragraph 0093).

"In a simplified database, database 1240' includes, for example, lists 1242, 1246 and 1248. This database arrangement may be advantageous where the database is stored in a local processor and/or a smart tag reader/writer where available memory capacity may be more limited than in another processor. In either a complete or simplified database, information relating to each writing of information to each smart tag

Art Unit: 2876

is communicated to a processor in real time or delayed, and may be periodic or aperiodic. Information may be communicated by any of the means described as well as by manual communication, e.g., by transporting the smart tag reader/writer and/or local processor and/or computer media containing the information stored in such smart tag reader/writer and/or local processor to another processor." (Paragraph 0107).

Chung teaches the following in regards to claims 19, and 23:

"Suitable relational database software include ACCESS and SQL Server database software which runs on conventional PC processors with standard operating systems, such as Windows-NT, both available from Microsoft Corporation of Redmond, Wash., as well as the ORACLE, SYBASE and INFORMIX database software. Preferably the database software is "Internet-ready" in that it includes features facilitating connection to and communication of information via the Internet." (Paragraph 0108).

Teachings disclosing the limitations of claims 21 and 22 are found above. Specifically, Chung teaches a computer processor for accessing a database including information regarding prescriptions and medications. It is inherent for the computer processor to run on a software program.

Chung's teachings above fail to teach both audibly disclosing the stored pharmaceutical information to a patient and additionally, including prescription counseling, and prompting the patient with an opportunity to accept or decline the counseling by interacting with an electronic input device.

Bain teaches the following in regards to claims 1, 9, and 21:

"An automated prescriptions dispensing system includes a patient interface portion, a dispensing portion and a control portion." (Abstract).

Bain teaches electronically disclosing the stored pharmaceutical counseling either visually and/or audibly to the patient.

Specifically, Bain teaches in paragraph 0020, a patient interface portion, which includes a display screen that conveys information to the patient. The information includes counseling information regarding the medication and potential side effects and/or drug interactions. Bain teaches that the counseling may either be in printed text, or a video of a pharmacist explaining proper use of the medication. A printer may also be provided for printing counseling or other information for the patient to take. Lastly, Bain teaches that a speaker may also be provided for giving counseling information to those who are visually impaired.

In view of Bain's teachings, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to combine Bain's teachings of generating an audible message when scanning a product with Chung's teaching of disclosing medical product information to a patient when the product's tag has been read. Additionally, one would be motivated to offer prescription counseling when desired by the patient, when picking up prescriptions at the pharmacy. Chung teaches producing an alarm (paragraph 0058) when the patient should be warned that the medication scanned is not for them. One would be motivated to additionally include prescription counseling in cases where the patient needs to be warned about certain

medications. This way, patients will have a clear warning of dangerous medication interaction or side effect that the medication may cause.

Chung's teachings in combination with the teachings of Bain are discussed above. The combination fails to teach the counseling video to be an interactive step-wise video.

With respect to claim 1, Hooper teaches in the abstract a system for a customer to interactively view videos.

Hooper additionally teaches in column 1, lines 11-20, that there is a need to provide consumers with video services on-demand. The videos may include textual information, and educational programs. Hooper discloses that both video and audio may include the "on-demand" capabilities.

In column 2, lines 19-24, Hooper teaches that customers can view different portions of the selected video. More specifically, the customer can interactively and independently view any portion of the video and skip over entire portions of videos. (see column 3, lines 35-46).

In view of Hooper's teachings, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to modify Bain's pharmaceutical counseling video such that a customer can skip over various portions of the counseling video. Interactive videos are known in the art. Hooper teaches an example of an interactive video, which is used by a customer. Bain discusses in paragraph 0006, the motivation of not wasting the time of a customer. Therefore one would be motivated to have the pharmaceutical video taught by Bain be in the form of

Art Unit: 2876

an interactive video wherein the customer may skip over various portions of the video so that the customer does not need to waste time viewing portions of the video that are not needed.

5. Claims 7, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chung in combination with Bain and Hooper and in further view of Stewart (2003/0183683).

Chung's teachings in combination with the teachings of Bain and Hooper are discussed above. The combination fails to teach recording an electronic signature of the patient.

With regards to claims 7, 20, and 24, Stewart teaches in figure 5, a digital signature capture means or signature pad 510. The pad is coupled to the computer means 504 and is used to capture the signature of the donor, collector, or other personnel.

In view of Stewart's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Stewart's digital signature capturing device in combination with the teachings of Chung, Bain, and Hooper. One would be motivated to additionally include an electronic signature capturing device in order to authenticate the patient before administering the prescription.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung in combination with Bain and Hooper and in further view of Kaafarani et al (2004/0078237), hereinafter Kaafarani.

Chung's teachings in combination with the teachings of Bain and Hooper are discussed above. The combination fails to allow the patient the interaction option of speaking to the pharmacist.

With respect to claim 18, Kaafarani teaches in paragraph 0020, providing the patient an optional step of dialing direct from the module to speak with a customer service representative or, if necessary, to speak with a pharmacist or pharmacy technician.

In view of Kaafarani's teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the patient the option of speaking to the pharmacist (informing a pharmacist of an interaction of the patient). Although the automatic or commanded information is beneficial, the patient may additionally have questions for the pharmacist. One would be motivated to include the option of speaking to the pharmacist for the above reason.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung in combination with Bain and Hooper and in further view of Wallace et al (2004/0210341), hereinafter Wallace.

Chung's teachings in combination with the teachings of Bain and Hooper are discussed above. The combination fails to specifically teach that the counseling complying with state law.

Wallace teaches the following in regards to claim 26:

"Per the regulations, "complimentary starter dose" means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is

provided to a dispensing prescriber free; of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients."

(Paragraph 0274).

In view of Wallace's teachings it would have been obvious to one of ordinary skill in the art at the time the invention to ensure that the counseling taught by Bain is in compliance with state law as is taught by Wallace. One would be motivated to comply with state laws in order to ensure that the safety of the patient is a top priority. Additionally, it is clear that any counseling provided by a pharmacy would comply with state law requirements for prescription counseling.

Response to Arguments

8. Applicant's arguments filed August 14, 2006 have been fully considered but are moot in view of the new ground(s) of rejection. Applicants have amended claim 1 to include the limitation of the counseling video to be interactive, whereby a customer can chose which portion of the video to view. Bain teaches providing customers a video for prescription counseling so that less time is wasted waiting to speak to a pharmacist. It is not taught however that Bain's video includes an interactive capability. Hooper has been provided to teach the interactive video limitation. It is believed that simply making the video interactive does not make the claim allowable over prior art, since interactive videos are well known. Additionally, claim 1 has been amended to include specific detailed counseling information. Bain however teaches in paragraph 0006 that the counseling includes information about the use of the medication and possible

interactions. Clearly this information may include the various information disclosed in applicant's claim 1.

With respect to claim 11, the video itself taught by Bain is a database containing all product information required to be provided for patient counseling. Modifying the video in order to make the video interactive even more clearly teaches that the video is a stored database. As is explained by Hooper, the interactive video is made possible because each portion of the video is electronically stored.

With respect to claim 7, applicant's arguments have been fully considered but they are not persuasive. Claim 7 simply includes the limitation that the patient provides a signature and electronically recording the signature of the patient. Although the applicant argues that Kaafarani does not teach going beyond authentication regarding receipt of a prescription medication, and that Kaafarani fails to teach providing a historical record of acquired patient counseling, this limitation is not currently disclosed in claim 7.

With respect to claim 26, applicant's arguments have been fully considered but they are not persuasive. It is obvious that any prescription counseling given at a legal pharmacy would comply with state law. The Wallace reference is only provided to show that is none in the art that any prescription or medical related products would comply with state and federal law.

Applicant's arguments with respect to claims 2 and 25 have been fully considered and are persuasive. Therefore the rejection of claims 2, 3, 6, 9, 10, and 25 has been withdrawn.

Allowable Subject Matter

9. Claims 2, 3, 6, 8, 10, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

The following is an examiner's for allowance: Although Chung in combination with Bain and Hooper teaches a method for providing pharmaceutical information to a patient the above identified prior art of record, taken alone, or in combination with any other prior art, fails to teach or fairly suggest the specific features of claims 2, 3, 6, 8, 10, and 25 of the present claimed invention. Specifically, prior art fails to teach in addition to electronically prompting a patient with a first message, wherein the first message provides the patient with an interactive choice of accepting or declining pharmaceutical counseling, establishing a historical record for the patient counseling interaction. Prior art further fails to specifically teach storing the patient's selection of accepting or declining the prescription counseling. The above limitations are not disclosed in prior art and moreover, one of ordinary skill in the art would not have been motivated to come to the claimed invention.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Allyson N. Trail* whose telephone number is (571) 272-2406. The examiner can normally be reached between the hours of 7:30AM to 4:00PM Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee, can be reached on (571) 272-2398. The fax phone number for this Group is (571) 273-8300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [allyson.trail@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35

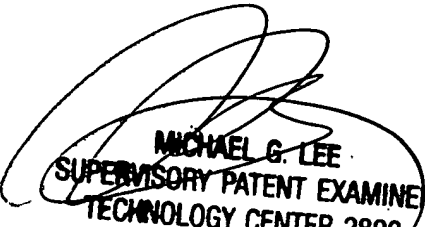
Art Unit: 2876

U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG

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aj

Allyson N. Trail
Patent Examiner
Art Unit 2876
February 16, 2007


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